K023519

12 510(k) Summary JAN 16 2003

Radionics VariLink 2 510(k) Summary

This summary of the 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. 807.92.

1.0 The submitter of this premarket notification is:

Kevin J. O'Connell
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Radionics, a division of Tyco Healthcare Group LP
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This summary was prepared on October 16, 2002.

2.0 The name of the device is the Radionics VariLink 2. The common name is Radiotherapy beam shaping block, and its classification name is Medical charged-particle radiation therapy system.

3.0 The above device is substantial equivalent to the Radionics ConforMAX MMLCVR1 was cleared via 510(k), K993594, on December 15, 1999.

4.0 The device is an optional accessory for the Radionics Mini-Multileaf Collimator (MMLC), mounted on a Varian C-Series Linear Accelerator (Linac). VariLink 2 allows Intensity Modulation Radiation Therapy (IMRT) functionality to be used on a Varian Linac. The Radionics' Treatment Planning software generates treatment plans with segmented beams, in which the intensity within the irradiation field is not constant (as in conventional treatments) but varies across the field. This requires the LINAC to suspend the beam between segments to allow the MMLC to change fields. VariLink 2 uses the Varian gating board to suspend the beam to allow MMLC to change the shape of the field.

5.0 The device is intended for use in stereotactic, conformal, computer planned, LINAC (linear accelerator) based radiation. The indications for use are: The VariLink 2 MMLC is intended to assist the radiation oncologist team in the delivery of radiation to well defined target volumes while sparing surrounding normal tissue and critical organs from excess radiation. With Radionics' Treatment Planning Software, the MMLC enables static conformal treatments to be performed with finely shaped field patterns.

6.0 System testing verifies that the device is ready for clinical use. A rigorous test of the functionality of VariLink 2 was conducted using a Varian C-Series Linac with the Gating Board Interface.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 2003

Mr. Kevin J. O'Connell
Senior Regulatory Associate
Radionics, A Division of Tyco Healthcare
22 Terry Avenue
BURLINGTON MA 01803-2516 USA

Re: K023519
Trade/Device Name: Radionics VariLink 2
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: October 17, 2002
Received: October 21, 2002

Dear Mr. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ODE Indications for Use Statement

510(k) Number (if known): K023519

Device Name: Radionics VariLink 2 MMLC

Indications for Use:

The Varilink 2 MMLC is intended to assist the radiation oncologist team in the delivery of radiation to well defined target volumes while sparing surrounding normal tissue and critical organs from excess radiation. The Varilink 2 MMLC can be used as part of IMRT (Intensity Modulated Radiotherapy) or general conformal radiation treatment.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR § 801.109)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023519